THIS OPINION WAS NOT WRITTEN FOR PUBLICATION

The opinion in support of the decision being entered today (1) was not written for publication in a law journal and (2) is not binding precedent of the Board.

Paper No. 20

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE BOARD OF PATENT APPEALS
AND INTERFERENCES

Ex parte JOSEPH P. D'ANGELO and HENRY SCHUR

Appeal No. 95-2379
Application 07/927,837[1]

ON BRIEF

Before STONER, Chief Administrative Patent Judge, and GARRIS and THIERSTEIN, Administrative Patent Judges.

THIERSTEIN, Administrative Patent Judge.

DECISION ON APPEAL

This is a decision on an appeal[2] under 35 U.S.C. § 134 from the rejection of claims 1, 4, 5, 7 through 17 and 21 through 27,

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[1] Application for patent filed August 10, 1992. According to appellants, this application is a continuation-in-part of Application 07/865,309, filed April 8, 1992.

[2] Notice of Appeal filed August 15, 1994.

all the claims remaining in the application[3] under the provisions of 35 U.S.C. § 112 and 35 U.S.C. § 103.[4] We *reverse*.

The claimed invention relates to a multidose transdermal drug delivery assembly. Claims 1, 7, 21 and 23 are all the independent claims on appeal. We consider independent claims 1 and 7 to adequately illustrate the subject matter on appeal. These claims are reproduced and attached as Appendix A to this opinion.

The references relied upon by the examiner are:

Allison et al. (Allison)	4,460,368	July 17, 1984
Kwiatek et al. (Kwiatek)	4,573,996	Mar. 4, 1986
Gale et al. (Gale)	4,904,475	Feb. 27, 1990
Heiber et al. (Heiber)	4,917,676	Apr. 17, 1990
Nelson et al. (Nelson)	4,917,688	Apr. 17, 1990
Katz et al. (Katz)	5,028,435	July 2, 1991
Fischel-Ghodsian	5,071,704	Dec. 10, 1991

The subject matter on appeal is directed to a multidose transdermal drug delivery assembly comprising a laminate composite. Essentially the assembly is a transdermal patch that

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[3] Claims 18 through 20 were canceled in Paper No. 4 as nonelected claims in group II of a restriction requirement in the administrative record, and claims 2, 3 and 6 were canceled in Paper No. 6.

[4] Final Office Action mailed April 13, 1994 and the Examiner's Answer mailed August 6, 1996 (hereinafter "answer") replacing the Supplemental Answer mailed June 16, 1995 and the Answer mailed November 30, 1994. The last mentioned Answer was determined to be in noncompliance with the applicable procedure by the Board of Patent Appeals and Interferences, in an order mailed July 29, 1996, remanding the application for consideration of new grounds of rejection which (at that time) had not been formally approved by the Supervisory Primary Examiner.

is adhered to a clear area of the skin and the drug is continually absorbed through the skin into the bloodstream for systemic distribution. In this invention the laminate composite includes multiple unit-dose reservoirs from which absorption occurs. A key feature of the assembly is an enclosing means related to each reservoir for activating respective unit doses of the drug active from each reservoir to be transdermally administered from the reservoir through a permeable membrane on either a transfer gel layer or a diffusible matrix. This layer or matrix is juxtaposed onto the skin by an adhesive means adhering the laminate composite thereto. In independent claims 1 and 21, the enclosing means are individual resealable strips disposed on each reservoir that peel back to activate respective unit doses of the drug from each reservoir. In independent claims 7 and 23, the enclosing means are individual sealing strips disposed between the reservoirs and the permeable membrane. These strips are removable from the assembly thereby activating respective unit doses for release of the drug from each reservoir. The laminate composite of claims 1 and 7 has a transfer gel layer juxtaposed between the permeable membrane and the surface of the skin, and the laminate composite of claims 21 and 23 has a diffusible matrix in place of the transfer gel layer.

Claims 1, 4, 5, 7 through 17 and 21 through 27 stand rejected under 35 U.S.C. § 112, first paragraph,[5] as based upon a specification which is objected to (answer, page 4, second paragraph, line 3) on the same statutory basis for failing to provide "support for the invention as is now claimed." Specifically, it is the examiner's position (answer, page 3, line 20 through page 4, line 3) that:

> There is no support in the originally filed specification for the language describing reservoirs "in a spaced-apart relationship with said transfer gel layer". Similarly, there is not support for the language describing the peeling back of the strips "while said laminate [composite] is disposed on the patient's skin". Appellant has been requested to indicate page and line number where found in the original specification.

In response, the appellants take the position that the support need not be verbatim and rely upon the disclosure as originally filed comprising the specification with the abstract, the claims and the drawings (brief,[6] page 11, last sentence).

We understand the examiner's rejection to be based upon the description requirement in the first paragraph of 35 U.S.C.

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[5] The examiner's objection under 35 U.S.C. § 132 to the amendment filed January 31, 1994, that twice amends claims 1, 7, 21 and also amends claim 23, for introducing new matter into the specification is subsumed by the rejection under 35 U.S.C. § 112, first paragraph. See Manual of Patent Examining Procedure (MPEP) § 2163.06 (6th ed., Rev. 2, July 1996).

[6] Filed October 20, 1994.

§ 112. As stated in In re Bowen, 492 F.2d 859, 864, 181 USPQ 48, 52 (CCPA 1974), the description requirement of 35 U.S.C. § 112, first paragraph "is that the invention claimed be described in the specification as filed." It is not necessary that the claimed subject matter be described identically, but the disclosure originally filed must convey to those skilled in the art that the applicant had invented the subject matter later claimed. See In re Wilder, 736 F.2d 1516, 222 USPQ 369 (Fed. Cir. 1984).

In the present instance, we agree with appellants that a spaced-apart relationship between the transfer gel layer and the resealable strips is shown in the drawings (brief, page 12, lines 1-5). We note the examiner's concern that number 11 is not visible on the Figure 2. However, we believe that Figures 2 and 4 cited by appellants together with Figure 1, even though Figure 4 shows a different embodiment from Figures 1 and 2 (Figures 1, 2, and 4 are attached as Appendix B), and the description (specification, page 20, lines 19-25) that:

> The unit dose cells 7 are closed to include the unit dose of encapsulated medicament 8 and gel matrix 18 by the overlaid tear strip 5 and the underlying permeable membrane 13. If necessary, the permeable membrane 13 may be utilized to control the rate of passage of encapsulated medicament 8 from the unit cell 7 into the diffusible matrix or transfer gel 11 after activation of the unit dose.

leave no doubt that the unnumbered space between 12 and 13 in Figure 2 is the transfer gel 11. Our opinion is reinforced by the disclosure in the specification, page 21, lines 10-15, that "[a]s the tear strip 5 is pulled back, the frangible medicament capsules are ruptured, thereby releasing the medicament 8, which diffuses through the permeable membrane 13, into the transfer gel 11 and through a patch/skin interface membrane 12 and is ready for absorption into the skin." It is clear that the unit dose cells 7 and permeable membrane 13 are between the tear strip 5 and the transfer gel in Figure 2. Even the examiner appears to recognize this at least in part in the statement that, "[w]hat is depicted is an underlying permeable membrane" (answer, page 5, lines 11-12). In this case, it is our view that "spaced" in "spaced apart relationship," can be broadly read as "not contiguous with another." Thus, we find the disclosure provides support for the claim 1 language "in a spaced-apart relationship with said transfer gel layer."

With regard to the phrase "while said laminate composite is disposed on the patient's skin" in each of the independent claims 1, 7, 21 and 23, it is the position of the examiner that the specification does not clearly describe placing the patch on the skin and then peeling back or removing the strips (answer, sentence bridging pages 5 and 6). Initially, it should be noted

that lack of literal support, in and of itself, is not sufficient to establish lack of adequate descriptive support. The question, therefore, is whether description of the properties and function described in appellants' specification would suggest to a person of ordinary skill in the art that the invention includes the use added here without introducing prohibited new matter. In re Smythe, 480 F.2d 1376, 1384, 178 USPQ 279, 285 (CCPA 1973).

Appellants (brief, page 13, lines 6-10 and 19) particularly point to the specification as follows:

Page 10, first full paragraph, which reads:

> In other words, the drug delivery assembly of this invention comprises a laminate composite having therein a series of at least two compartments, each compartment being a reservoir for a unit-dose of the drug-actives to be transdermally administered, adhesive means for adhering the support with the open face of the reservoir containing the drug actives being juxtaposed to the skin. Individual resealable closure means are provided containing the drug actives within the reservoir.

Page 16, last paragraph, which reads:

> In animal tests patches containing insulin microencapsulated as above, have been applied to the shaved skin of a series of insulin-deficient animals and the microcapsules have been disrupted to free the insulin into contact with the shaved skin. Within 30 minutes, all animals exhibited measurable insulin levels in the blood. By adjustment of insulin concentrations in the microcapsules, therapeutic blood levels could be realized.

Page 21, first paragraph, which reads:

> Each unit dose is activated by a two-step process. Step #1 is the removal of a security strip segment 2 by pulling back on a tab 14, which thereby exposes a tear-and-release tab 3. The purpose of the security strip 2 is to prevent any accidental release of the medicament. In step #2, each unit dose is individually activated by pulling up the tear and release tab 3 located on the end of each tear strip 5. When the tear strip 5 is pulled back to its attachment area 6, activation indicator 4 is released to provide the patient with a confirmation of the full activation of medicament 8. As the tear strip 5 is pulled back, the frangible medicament capsules are ruptured, thereby releasing the medicament 8, which diffuses through the permeable membrane 13, into the transfer gel 11 and through a patch/skin interface membrane 12 and is ready for absorption into the skin. The skin patch interface membrane 12 may be completely pervious to the contents of the cell. The transfer gel 11 may or may not contain a steady state medicament in appropriate dosage as required by the individual patient.

Page 22, first full paragraph, which reads:

> The entire assembly is fastened to the skin by an adhesive border 10 which is adhesive coated to ensure positioning on the skin. The adhesive border 10 is preferably formulated to allow for repositioning of the assembly.

Page 23, lines 1 through 8, which reads:

> In step #2 each unit dose is individually activated by pulling on pull pouch tab 15 until pull pouch strip 16 is removed from the assembly 20. Removal of the impervious pull pouch strip 16 allows the pull pouch medicament 22 to diffuse through the permeable membrane 13, into the transfer gel 11 and thru [sic] the patch/skin interface membrane 12 and is ready for absorption into the skin.

Page 24, first full paragraph, which reads:

> The basal attachment membrane 25 extends past the patch/skin interface membrane 12 providing a surface to attach the assembly 20 to the skin via the border adhesive to ensure positioning on the skin. The adhesive is preferably formulated to allow for repositioning of the assembly.

The abstract at page 31 which reads:

> A multidose transdermal drug delivery system comprises a laminate composite with a plurality of compartments. Each compartment is a reservoir for a unit dose of a drug active to be transdermally administered. The assembly is adhesively secured to the skin of a patient. Individual seals are provided for resealably enclosing the drug active in each of the reservoirs. The individual enclosing seals are removable to release the unit dose into contact with the skin of the patient and are actuable to control the transdermal absorption of the drug actives.

Finally, page 4, last two lines, which read:

> It is an object of this invention to provide a multiple unit-dose transdermal patch assembly.

We find these passages neither unclear nor contradictory in their disclosure of strips that can be peeled back or removed for activating respective unit doses in the manner expressed by

the language “while said laminate composite is disposed on the patient's skin.” According to the examiner (answer, page 6, lines 1-4):

> Indeed, common sense says that the strip is removed before placing the laminate on the skin. Otherwise, if the laminate is adhered to the skin, how is the strip removed? There is no doubt that the membrane is meant to be placed on the skin.

We do not know what is in the mind of the examiner, since first placing the laminate on the skin does not prevent subsequent removal of the strip. In the same way, first placing the membrane on the skin does not then prevent removal of the strip. Thus, the examiner’s conclusion that common sense says the strip is removed before placing the laminate on the skin is not supported by the examiner’s stated facts.

Thus, in light of the appellants' disclosures and arguments that even though the specification as originally filed does not provide verbatim support for the language “in a spaced-apart relationship with said transfer gel layer” and “while said laminate composite is disposed on the patient's skin,” we agree with appellants that the written description requirement of 35 U.S.C. § 112, first paragraph, is met for the language in issue here.

Claims 1, 4, 5, 7,[7] 8, 9, 15, 16 and 21 through 26 are rejected under 35 U.S.C. § 103 as unpatentable over Gale in view of Heiber and further in view of Nelson.

The examiner relies on Gale for the disclosure of a transdermal drug delivery system that is a single aqueous drug reservoir comprising a porous support member, a transfer gel layer on the support member and a permeable membrane on the gel layer with a porous adhesive that constitutes a diffusible matrix, and also maintains the system in contact with the skin. Heiber is relied on by the examiner for teaching a transdermal

[7] Although claim 7 was included by the examiner in the final rejection, Paper No. 9, claim 7 was not mentioned as being among the claims rejected in the statement contained in the examiner's answer. This appears to be an inadvertent error. We treat claim 7 as being included in this rejection.

drug delivery system comprising multiple reservoirs having burstable seals or membranes between reservoirs, enclosing means, means for controlling transdermal absorption, small periphery reservoirs and visual indicator means. The examiner states (answer, page 7, last paragraph) that:

> Nelson teaches a transdermal delivery bandage comprising control means for controlling the surface contact area between the active agent and the dermal surface. The control means are selectively removable cover segments which are removed manually (column 2, lines 47-62 and figure 3 and Applicants figure 1).

We have carefully considered the examiner's position (answer, page 8, lines 2-8) that:

> The motivation for combining the removable cover means of Nelson with the transdermal device of Gale in view of Heiber is provided by Nelson, who discloses that "this feature enables the bandage...to provide a varying number of doses of particular drug...without the necessity for manufacturing an array of bandages having different doses and the concomitant storage and dispensing costs [sic,"] (column 2, lines 25-30).

However, such a combination does not produce the appellants' *claimed* subject matter. As appellants argue (brief, page 16 and page 17, lines 1-3 and lines 13-17) Nelson discloses removable strips that are disposed on the surface of the patch that is to contact the skin. This is different from the claimed strips that are "disposed on said reservoirs" (claim 1, line 19) or that are disposed "between said reservoirs and said permeable membrane" (claim 7, lines 20-21). Clearly, the claimed strips

are not on the surface of the patch that is to contact the skin. Although this argument is not specifically addressed, the examiner, nevertheless, concludes that "[h]owever, even regardless of the orientation of the strips, it is clear that both Nelson and Appellant[s] utilize the strips for the same purpose" (answer, page 12, lines 10-11).

Appellants further contend that Nelson's strips would have provided selected dosages if those strips are removed prior to the application of the patch to the skin and therefore "the more functional language at the end of claims 6 [sic, claim 1] 7, 21 and 23 very clearly distinguishes over any combination of the art of record and it describes the user activation function subsequent to the application of the patch"[8] (brief, page 17, lines 9-12). The examiner responds that "[t]his argument is not persuasive as it is this very theory which has been rejected under New Matter" (answer, first full sentence page 13).

The examiner has not asserted that it would have been obvious to so combine the above discussed references as to obtain the claimed subject matter and in particular the claimed features which activate respective unit doses "while said

[8] Apparently appellants are referring here to the language "while said laminate composite is disposed on the patient's skin."

laminate composite is disposed on the patient's skin." Instead, the examiner appears to be of the view she is at liberty to ignore the claim features which she regards as "new matter." This is incorrect. It is well settled that all words in a claim must be considered in judging the patentability of that claim against the prior art. In re Wilson, 424 F.2d 1382, 165 USPQ 494 (CCPA 1970). Because nothing in the prior art upon which the examiner has relied would have made obvious the claimed construction, the rejection of claims 1, 4, 5, 7, 8, 9, 15, 16 and 21 through 26 under 35 U.S.C. § 103 must be reversed.

Additionally, we have reviewed the subject matter of Allison, Kwiatek, Katz and Fischel-Ghodsian applied by the

examiner in the rejection of dependent claims 10, 11 through 14, 17 and 27 but find nothing therein which makes up for the deficiencies of Gale, Heiber and Nelson. Accordingly, we cannot sustain the § 103 rejections of claims 10, 11 through 14, 17 and 27.

The decision of the examiner is reversed.

REVERSED

BRUCE H. STONER, JR., Chief Administrative Patent Judge	)	
BRADLEY R. GARRIS Administrative Patent Judge	)	BOARD OF PATENT APPEALS AND INTERFERENCES
JOAN THIERSTEIN Administrative Patent Judge	)	

Appeal No. 95-2379
Application 07/927,837

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APPENDIX A

1. A multidose transdermal drug delivery assembly, comprising a laminate composite of

- a transfer gel layer;
- a permeable membrane disposed on said transfer gel layer;
- overlaid impervious drug enclosure means for receiving and protectively enclosing a drug active to be transdermally administered;
- said drug enclosure means and said permeable membrane defining a plurality of compartments therebetween defining reservoirs for respective unit doses of the drug active;
- individual activation means for releasing unit doses of the drug active from respective ones of said compartments for contacting with a patient's skin; and
- means for enclosing the drug active in each of said reservoirs, said enclosing means being individual resealable strips disposed on said reservoirs in a

APPENDIX A (Cont'd.)

spaced-apart relationship with said transfer gel layer for activating respective unit doses by peeling back respective ones of said strips while said laminate composite is disposed on the patient's skin.

7. A multidose transdermal drug delivery assembly, comprising a laminate composite of

- a transfer gel layer;
- a permeable membrane disposed on said transfer gel layer;
- overlaid impervious drug enclosure means for receiving and protectively enclosing a drug active to be transdermally administered;
- said drug enclosure means and said permeable membrane defining a plurality of compartments therebetween defining reservoirs for respective unit doses of the drug active;

APPENDIX A (Cont'd.)

- individual activation means for releasing unit doses of the drug active from respective ones of said compartments for contacting with a patient’s skin; and
- means for enclosing the drug active in each of said reservoirs,

said enclosing means being individual sealing strips disposed between said reservoirs and said permeable membrane, said strips being removable from said assembly through a resealing strip for activating respective unit doses while said laminate composite is disposed on the patient’s skin.